DAC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#16

Re: Gleevec
Docket No.: 02E-0024

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

OCT 31 2002

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,521,184, filed by Novartis Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Gleevec, the human drug product claimed by the patent.

The total length of the regulatory review period for Gleevec is 1,098 days. Of this time, 1,025 days occurred during the testing phase and 73 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 10, 1998.

   The applicant claims April 9, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 10, 1998, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: February 27, 2001.

   FDA has verified the applicant's claim that the new drug application (NDA) for Gleevec (NDA 21-335) was initially submitted on February 27, 2001.

3. The date the application was approved: May 10, 2001.

   FDA has verified the applicant's claim that NDA 21-335 was approved on May 10, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas Hoxie
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